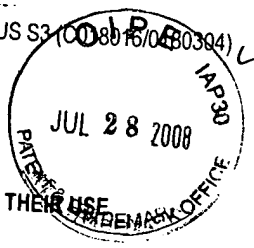
July 24, 2008

Docket No.: F2842 US S3 (0080[illegible]/0480394)



In re Patent Application of :
Michael BARDROFF *et al.*
Serial No.: 10/505,313
Filed: August 20, 2004
For: **ANTI-AMYLOID BETA ANTIBODIES AND THEIR USE**

Enclosed:

1. Supplemental Response To Office Action, Including Summary of Examiner's Interview, Amendment and Request For Extension of Time with certificate of mailing (16 pages including duplicate pg. 1) with Exhibit 1 (3 pages)
2. $590.00 check to cover extension of time fees; and
3. Return Postcard

PLEASE DATE STAMP AND RETURN TO ACKNOWLEDGE RECEIPT

JZang:mh

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,313	03/07/2005	Michael Bardroff	F2842 US S3 (C018016/0180	1924

7590 10/14/2008

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10505313 (C018016/0180	3/7/2005	BARDROFF ET AL.	F2842 US S3

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EXAMINER	
Gregory S. Emch	
ART UNIT	**PAPER**
1649	20081009

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Election/Restrictions
The amendment filed on 28 July 2008 canceling all claimed subject matter drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). Applicants have already received an action on the merits for the elected species of the MSR-7 antibody. Applicants are reminded that they were required to elect one antibody species in the restriction requirement dated 05 June 2007 (note: one antibody, NOT family of antibodies). According to Applicants' specification (e.g. Figure 4 and sequence listing), the 6 CDR sequences for the elected MSR-7 antibody are L-CDR1=SEQ ID NO: 143, L-CDR2=SEQ ID NO: 144, L-CDR3=SEQ ID NO: 18, H-CDR1=SEQ ID NO: 146, H-CDR2=SEQ ID NO: 147 and H-CDR3=SEQ ID NO: 24. Thus, newly amended claim 1 and newly presented claim 41 (as of amendment dated 02 July 2008) and dependent claims are directed to an invention(s) that is independent or distinct from the invention originally claimed because none of the claims encompass the CDR sequences of the elected MSR-7 species.
Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.
Advisory Information
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.
/G.E./
Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
09 October 2008

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646

PTO-90C (Rev.04-03)

Docket No.: F2842 US S3 (C018016/0180304)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Michael BARDROFF *et al.*	)	Examiner: G. S. Emch
Serial No.: 10/505,313	)	Art Unit: 1649
Filed: August 20, 2004	)	
For: **ANTI-AMYLOID BETA ANTIBODIES AND THEIR USE**		

New York, New York
January 13, 2009

RESPONSE TO OFFICE COMMUNICATION, INCLUDING SUMMARY OF EXAMINER INTERVIEW, AND REQUEST FOR EXTENSION OF TIME

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a response to the Office Communication mailed October 14, 2008, which set a one-month shortened statutory period for response. As requested by the Examiners, the remarks presented herein serve to memorialize the clarifications and understandings reached during the Examiner Interview conducted on December 3, 2008.

A two-month extension of time to respond to the Office Communication is hereby requested. Accordingly, this response is filed timely upon mailing, with an executed certificate of mailing, on or before January 14, 2009. 37 CFR §§ 1.8 and 1.136. Enclosed is a check in the amount of $490. 37 CFR § 1.17. Please charge any required extension-of-time fees, or any other fees, not otherwise paid by check to Deposit Account No. 02-4467. A duplicate copy of this sheet is enclosed.

Please amend the application as follows:

AMENDMENTS TO THE SPECIFICATION: None.

AMENDMENTS TO THE CLAIMS: None. List of claims begins on page 3 of this paper.

REMARKS begin on page 8 of this paper.

LISTING OF CLAIMS:

Claim 1. (Previously Presented) An antibody molecule capable of specifically recognizing two regions of the β-A4 peptide/Aβ4, wherein the first region comprises the amino acid sequence AEFRHDSGY as shown in SEQ ID NO: 1 or a fragment thereof and wherein the second region comprises the amino acid sequence VHHQKLVFFAEDVG as shown in SEQ ID NO: 2 or a fragment thereof, wherein said antibody molecule comprises

(a) a variable V_L-Region comprising complementary determining regions, L-CDR1, L-CDR2, L-CDR3, wherein:

(1) L-CDR1 comprises a sequence selected from the group consisting of SEQ ID NOs: 96, 160, 175-177, 180, 189-190, 200-201, and 206-210;

(2) L-CDR2 comprises a sequence selected from the group consisting of SEQ ID NOs: 97 and 161; and

(3) L-CDR3 comprises a sequence selected from the group consisting of SEQ ID NOs: 18, 79, 81, 95, 149, 151-156, 158-159 and 166; and

(b) a variable V_H-Region comprising complementary determining regions, H-CDR1, H-CDR2, H-CDR3, wherein:

(1) H-CDR1 comprises a sequence selected from the group consisting of SEQ ID NOs: 99 and 163;

(2) H-CDR2 comprises a sequence selected from the group consisting of SEQ ID NOs: 100, 164, 167-169, 170-174, 179, 181-182, 184-188, 192-197, 199 and 204; and

(3) H-CDR3 comprises a sequence selected from the group consisting of SEQ ID NO: 24.

Claim 2. (Original) The antibody molecule of claim 1, wherein said antibody molecule recognizes at least two consecutive amino acids within the two regions of β-A4.

Claim 3. (Previously Presented) The antibody molecule of claim 1, wherein said antibody molecule recognizes in the first region an amino acid sequence selected from the group consisting of EF, EFR, FR, and SEQ ID NOs: 415 – 418, and in the second region an amino acid sequence selected from the group consisting of LV and SEQ ID NOs: 419 - 423.

Claim 4. (Previously Presented) The antibody molecule of claim 1, wherein said antibody molecule comprises a variable V_H-region comprising a sequence selected from the group consisting of SEQ ID NOs: 6, 37, 39, 41, 43, 89, and 425.

Claim 5. (Previously Presented) The antibody molecule of claim 1, wherein said antibody molecule comprises a variable V_L-region comprising a sequence selected from the group consisting of SEQ ID NOs: 12, 51, 53, 57, and 91.

Claim 6. (Cancelled).

Claim 7. (Previously Presented) The antibody molecule of claim 1, wherein said antibody is selected from the group consisting of MSR-7 and an affinity-matured version of MSR-7.

Claim 8. (Previously Presented) The antibody molecule of claim 1, wherein said antibody molecule is a full antibody (immunoglobulin), a F(ab)-fragment, a

$F(ab)_2$-fragment, a single-chain antibody, a chimeric antibody, a CDR-grafted antibody, a bivalent antibody-construct, a synthetic antibody or a cross-cloned antibody.

Claim 9. (Previously Presented) The antibody molecule of claim 1, wherein said two regions of β-A4 form a conformational epitope or a discontinuous epitope.

Claim 10. (Cancelled).

Claim 11. (Previously Presented) A nucleic acid molecule encoding an antibody molecule according to claim 1.

Claim 12. (Original) A vector comprising the nucleic acid molecule of claim 11.

Claim 13. (Original) A host cell comprising the vector of claim 12.

Claim 14. (Previously Presented) A method for the preparation of an antibody molecule comprising culturing the host cell of claim 13 under conditions that allow synthesis of said antibody molecule and recovering said antibody molecule from said culture.

Claim 15. (Previously Presented) A pharmaceutical or diagnostic composition comprising an antibody molecule according to claim 1 and a carrier or diluent.

Claim 16. (Previously Presented) The composition of claim 15, which is a pharmaceutical composition.

Claims 17-21. (Cancelled).

Claim 22. (Previously Presented) A kit comprising an antibody molecule according to claim 1, a nucleic acid molecule according to claim 11, a vector according

to claim 12 or a host cell according to claim 13, wherein the antibody, nucleic acid, vector or host cell is contained in at least one vial, bottle, container or multicontainer unit.

Claims 23-28. (Cancelled).

Claim 29. (Previously Presented) A composition comprising an antibody molecule produced by the method of claim 14.

Claim 30. (Previously Presented) The composition of claim 16 further comprising a pharmaceutically acceptable carrier and/or diluent.

Claims 31-40. (Cancelled).

Claim 41. (Previously Presented) An antibody molecule comprising

(a) a variable V_L-Region comprising complementary determining regions, L-CDR1, L-CDR2, L-CDR3, wherein:

(1) L-CDR1 comprises SEQ ID NO: 143;

(2) L-CDR2 comprises SEQ ID NO: 144; and

(3) L-CDR3 comprises SEQ ID NO: 95; and

(b) a variable V_H-Region comprising complementary determining regions, H-CDR1, H-CDR2, H-CDR3, wherein:

(1) H-CDR1 comprises SEQ ID NO: 146;

(2) H-CDR2 comprises SEQ ID NOs: 192; and

(3) H-CDR3 comprises SEQ ID NOs: 93.

Claim 42. (Previously Presented)The antibody molecule according to claim 41, wherein the antibody is of the IgG1 subtype.

Claim 43. (Previously Presented) The antibody molecule according to claim 41, wherein the variable V_H-region comprises SEQ ID NO: 89; and the variable V_L-region comprises SEQ ID NO: 91.

Claim 44. (Previously Presented) The antibody molecule according to claim 43, wherein the antibody is of the IgG1 subtype.

Claim 45. (Previously Presented) The antibody molecule according to claim 41, wherein the variable V_H-region comprises SEQ ID NO: 425; and the variable V_L-region comprises SEQ ID NO: 91.

Claim 46. (Previously Presented) The antibody molecule according to claim 45, wherein the antibody is of the IgG1 subtype.

Claim 47. (Previously Presented) A pharmaceutical composition comprising an antibody molecule according to claim 41 and a pharmaceutically acceptable carrier or diluent.

Claim 48. (Previously Presented) A pharmaceutical composition comprising an antibody molecule according to claim 44 and a pharmaceutically acceptable carrier or diluent.

Claim 49. (Previously Presented) A pharmaceutical composition comprising an antibody molecule according to claim 46 and a pharmaceutically acceptable carrier or diluent.

REMARKS

Summary of Office Communication and Examiner Interview

In the Office Communication dated October 14, 2008, the Examiner asserted that "[t]he amendment filed on 28 July 2008 canceling all claimed subject matter drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive." (Paper 20081009 at 1). The Examiner further asserted that "[a]ccording to Applicants' specification (e.g. Figure 4 and sequence listing), the 6 CDR sequences for the elected MSR-7 antibody are L-CDR1=SEQ ID NO: 143, L-CDR2=SEQ ID NO: 144, L-CDR3=SEQ ID NO: 18, H-CDR1=SEQ ID NO: 146, H-CDR2=SEQ ID NO: 147 and H-CDR3=SEQ ID NO: 24." (*Id.*) The Examiner concluded, "[t]hus, newly amended claim 1 and newly presented claim 41 (as of amendment dated 02 July 2008 [sic]) and dependent claims are directed to an invention(s) that is independent or distinct from the invention originally claimed because none of the claims encompass the CDR sequences of the elected MSR-7 species." (*Id.*)

On December 3, 2008, a telephonic Examiner's Interview was conducted between Stephen Haracz and Jihong Zang, Applicants' attorneys, and Examiners Emch and Kemmerer. The purpose of the interview was to clarify for the Examiners that the amended claims are drawn to the elected invention and thus are responsive. We thank the Examiners for their participation and stated understanding of the explanation. During the Interview, issues raised in the Office Communication dated October 14, 2008 were discussed. As requested by the Examiners, the explanations are hereby memorialized and set forth below.

The amended claims encompass the CDR sequences of MSR-7

As explained during the interview, amended claim 1 recites the six CDR sequences of MSR-7 antibody; the confusion is due to the fact that the SEQ ID NOs. recited in claim 1 are different from those noted by the Examiner. The sequence listing contains redundant SEQ ID NOs. for the same sequence. In an effort to simplify the claim, we omitted the redundant SEQ ID NOs., including, unfortunately, the particular SEQ ID NOs. recited by the Examiner in the Office Communication. However, the SEQ ID NOs. of the MSR-7 CDRs referenced by the Examiner set forth the same amino acids as the SEQ ID NOs. listed in claim 1, as shown in the chart below.

	SEQ ID NO. cited by the Examiner	Corresponding SEQ ID NO. listed in Claim 1	Sequence
L-CDR1	143	96	RASQSVSSSYLA
L-CDR2	144	97	GASSRAT
L-CDR3	18	18	FQLYSDPF
H-CDR1	146	99	GFTFSSYAMS
H-CDR2	147	100	AISGSGGSTYYADSVKG
H-CDR3	24	24	GKGNTHKPYGYVRYFDV

For a complete listing of the redundant SEQ ID NOs, the Examiner is referred to the chart submitted as Exhibit 1 of the Response mailed on July 24, 2008. The chart shows the sequences of the CDRs in columns 2, 4, 6, 8, 10, and 12 as well as the corresponding SEQ ID NOs. in columns 3, 5, 7, 9, 11, and 13.

In summary, the amino acid sequences of the six CDRs of MSR-7 are recited in claim 1, and they have already been searched and examined as stated in the

Office Communication. (Paper 20081009 at 1). Because the SEQ ID NOs. of the CDRs of the elected MSR-7 antibody are included in the amended claim 1, it is respectfully submitted that the Response mailed on July 24, 2008 is responsive.

Claims 41-49 closely correspond to the subject matter already searched

As we explained and as the Examiners acknowledged during the interview, the restriction requirement was understood to embrace a family of MSR-7 antibodies rather than a single parental antibody. Claim 41 was presented because MSR7.9.H.7 is an affinity matured version of MSR-7, having substantial structural identity to MSR-7.

Because MSR7.9.H.7 derives from MSR-7, the CDR sequences of the two antibodies are very similar. In fact, four of the six CDR sequences of MSR7.9.H.7 (L-CDR1, L-CDR2, H-CDR1, and H-CDR3) are identical to that of MSR-7 antibody, which has already been searched. The sequences of the two related antibodies are further compared in the chart below.

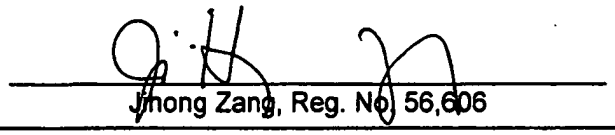
	MSR-7	MSR7.9.H.7
L-CDR1	RASQSVSSSYLA	same
L-CDR2	GASSRAT	same
L-CDR3	FQLYSDPF	LQIYNMPI
H-CDR1	GFTFSSYAMS	same
H-CDR2	AISGSGGSTYYADSVKG	AINASGTRTYYADSVKG
H-CDR3	GKGNTHKPYGYVRYFDV	same

As shown above, the similarity between MSR-7 and MSR7.9.H.7 goes beyond the 4 identical CDR sequences. A fifth CDR, H-CDR2, shares 13 of 17 residues (consensus sequence: AIXXSGXXTYYADSVKG).

Thus, four of the six CDR sequences recited in claims 41-49 have already been searched and examined on the merits. Further searches are not believed necessary to continue with claims 41-49. Therefore, we respectfully request that claims 41-49, which list the CDRs of MSR7.9.H.7, be considered because they closely correspond to the MSR-7, whose CDR sequences have already been searched and examined.

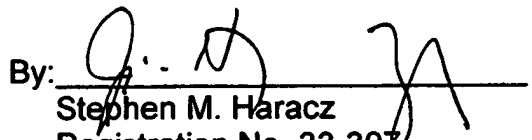
For the reasons set forth above, examination and allowance of the amended claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 13, 2009.



Jihong Zang, Reg. No. 56,606

Respectfully submitted,

By: 

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